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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/403,955 | 04/09/2001 | Evzen Kasafirek | CM-2206F | 7890 |

27752 7590 09/07/2005

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
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CINCINNATI, OH 45224

EXAMINER

KOSAR, ANDREW D

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1654

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/403,955 | KASAFIREK ET AL. | |
| | Examiner | Art Unit | |
| | Andrew D. Kosar | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-8 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20050823</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/13/01</u> . | 6) <input checked="" type="checkbox"/> Other: <u>notice to comply</u> . |

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DRAFT EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Betty Zea, on August 30, 2005.

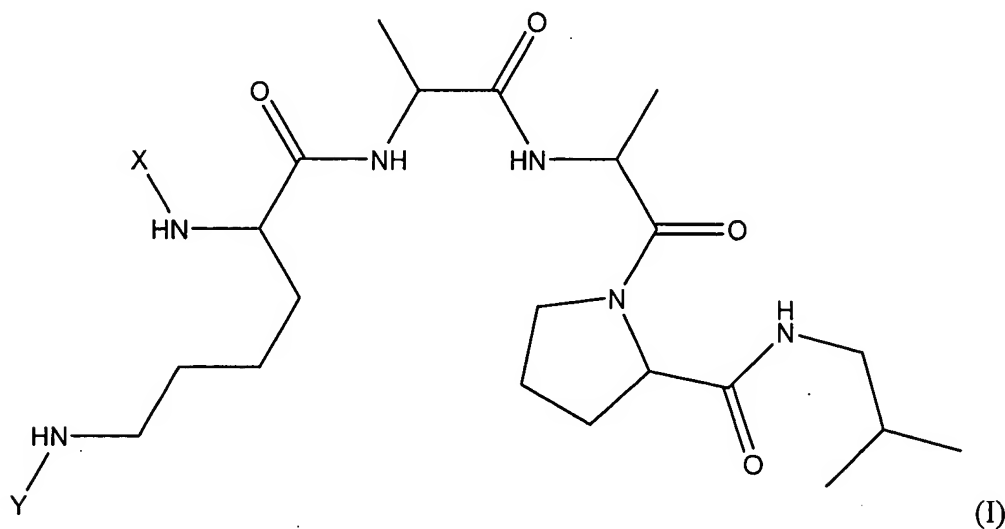
Claims 1-4 have been examined on the merits. Claims 1-4 have been cancelled and replaced with claims 5-8 which overcome 112, 2nd paragraph issues, and draft the claims in accordance with current US practice.

The application has been amended as follows:

CANCEL claims 1-4.

ENTER NEW CLAIMS 5-8 as follows:

5. (NEW) Oligopeptidic elastase inhibitors of formula (I):



Wherein:

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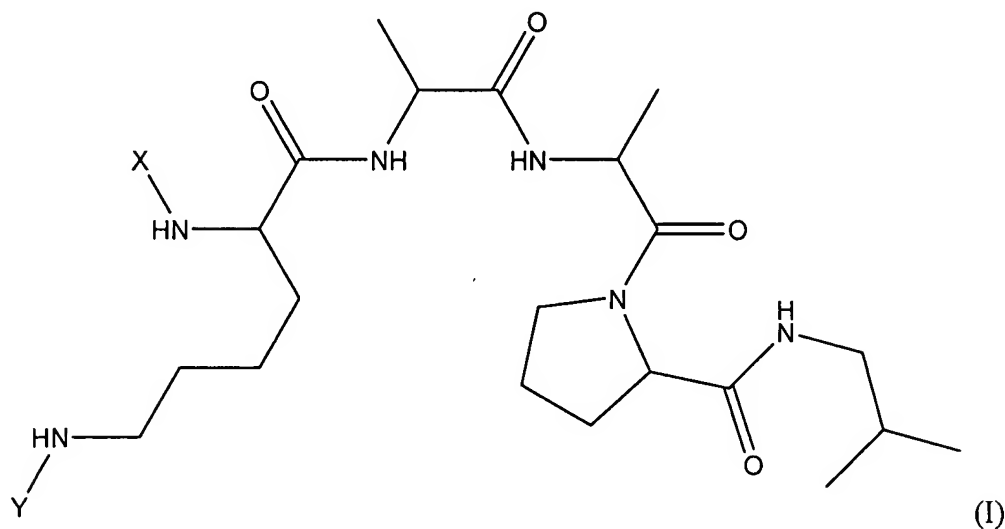
Reacting a compound of formula $A-X^1$, where X^1 is a halogen, with the ϵ -amino group of Lys;

Deprotecting the α -amino group of Lys; and

Reacting the α -amino group of Lys with succinic anhydride or glutaric anhydride;

Thereby forming the compound of formula (I), where X is B and Y is A.

7. (NEW) A method for the preparation of compounds of formula (I):



Wherein:

X is A;

Y is B;

A is a saturated acid of 8 to 16 carbon atoms; and

B is 3-carboxypropionyl or 4-carboxybutyryl;

The method comprising the steps:

Contacting a compound of formula A-Lys(W), where W is an ϵ -amino protecting group, with Ala-Ala-Pro-NH-iBu;

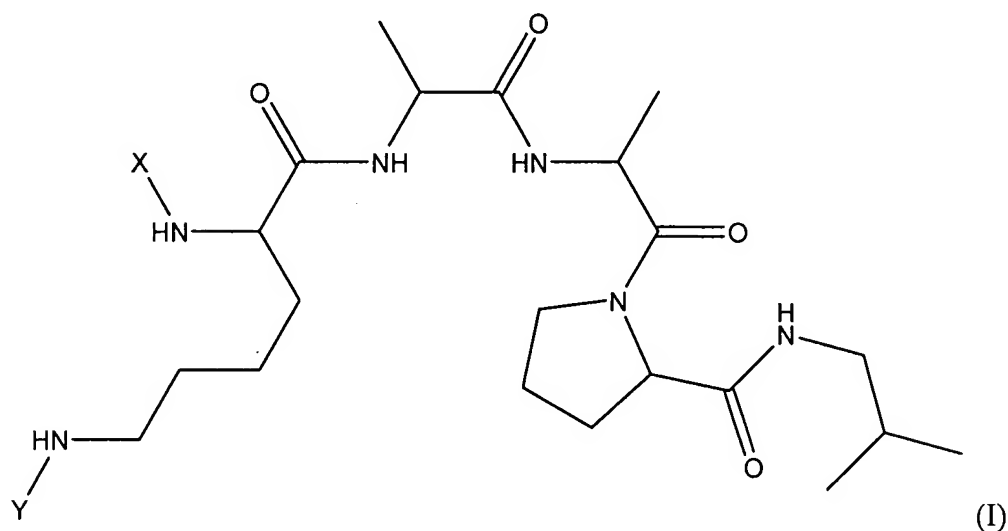
Deprotecting the ϵ -amino group of Lys; and

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Contacting the ϵ -amino group of Lys with succinic anhydride or glutaric anhydride;

Thereby forming the compound of formula (I), where X is A and Y is B.

8. (NEW) A method for the preparation of compounds of formula (I):



Wherein:

X is B;

Y is A-Ala;

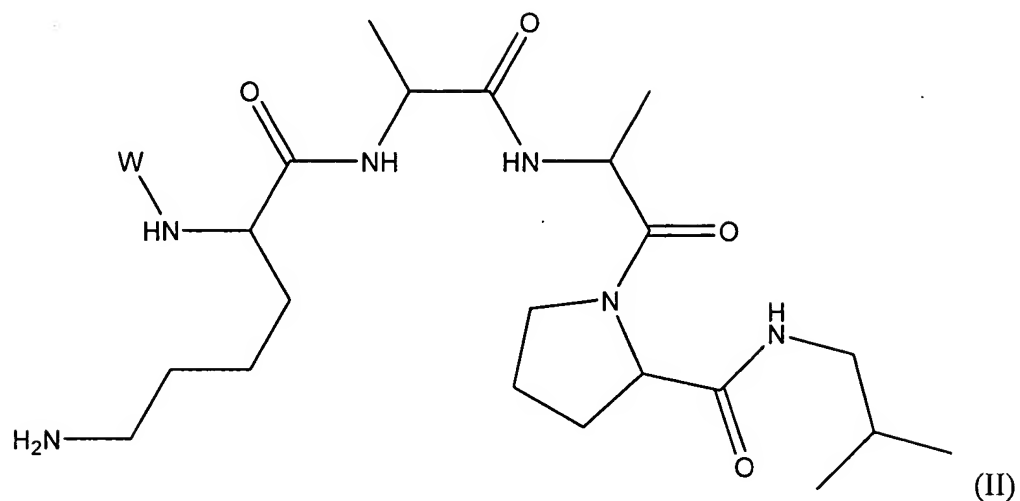
A is a saturated acid of 8 to 16 carbon atoms; and

B is 3-carboxypropionyl or 4-carboxybutyryl;

The method comprising the steps:

Contacting a compound of formula (II):

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where W is an α -amino protecting group, with A-Ala;

Deprotecting the α -amino group of Lys; and

Contacting the α -amino group of Lys with succinic anhydride or glutaric anhydride;

Thereby forming the compound of formula (I), where X is B and Y is A-Ala.

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The following is an examiner's statement of reasons for allowance:

The closest prior art, KASAFIREK (US Patent 4,528,133) teaches compounds undecanoyl-Asp-Ala-Ala-Pro-NH-iBu, butyryl-Asp-Ala-Ala-Pro-NH-iBu, and related compounds (e.g., Table 1), as well as the synthesis thereof (e.g. Example 8). Additionally, Kasafirek (US Patent 4,554,100) teaches related compounds (e.g. Table 2) and their synthesis. However, alone or in combination, Kasafirek does not teach or suggest replacing Asp, an acidic residue, with a basic residue, such as Lys, nor does it teach or suggest substitutions at the ϵ -amino group of Lys, with such groups as A-Ala, where A is a saturated acid of 8 to 16 carbons, or methods of making the instantly claimed compounds.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Sequence Compliance

Applicant is advised that the application is not in compliance with 37 CFR §§ 1.821-1.825.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR §§ 1.821- 1.825) in order to effect a complete response to this office action.

Specifically, as indicated in the attached *Raw Sequence Listing Report*, the 'features table' is incomplete for sequences 1-5, which should also be identified as 'Artificial Sequence' rather than 'artificialsequence'. Applicant should identify terminal amidation, modifications, etc. in the features field. Additionally, sequences in the specification which are identified in the sequence listing require sequence identifiers (SEQ ID NO:).

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Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
(<http://www.uspto.gov/ebc/efs/downloads/documents.htm>), EFS Submission User Manual – ePave)

2. Mailed to:
Mail Stop Sequence
Commissioner for Patents
PO Box 22313-1450
Alexandria, VA 22313-1450

Conclusion

This application is in condition for allowance except for the following formal matters:

Applicant has not fully complied with the sequence rules, as indicated *supra*.

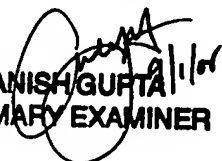
Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.


A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANISH GUPTA
PRIMARY EXAMINER


Andrew D. Kosar, Ph.D.
Art Unit 1654